

THE CLAIMS

Cancel claims 1-20

21. (Withdrawn) A method for determining the amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) that is necessary to increase glutathione synthesis or re-synthesis in a patient in need of such therapy, comprising the steps of:

- a) collecting a series of body fluid samples from a patient suspected of being in need of such treatment, wherein said body fluid samples are collected prior to the start of treatment, and daily after the start of treatment for about 14 days
- b) measuring the amount of lipid peroxide and pyroglutamic acid in said body fluid samples;
- c) comparing the amount of lipid peroxide and pyroglutamic acid in said body fluid samples with that of normal standards;
- d) measuring the amount of glutathione increase in blood samples;
- e) comparing the amount of glutathione in said blood samples with that of normal standards; and

wherein the normalization of lipid peroxide and pyroglutamic acid levels in said body fluid samples correlates with the synthesis or re-synthesis of glutathione in the patients receiving IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM).

22. (Withdrawn) A method for determining the amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) that is necessary to reduce urine pyroglutamic acid in a patient in need of such therapy, comprising the steps of:

- a) collecting a series of urine samples from a patient suspected of being in need of such treatment, wherein said samples are collected prior to the start of treatment, and daily after the start of treatment for about 14 days;
- b) measuring the amount of pyroglutamic acid in said samples;
- c) comparing the amount of pyroglutamic acid in said samples with that of a normal standard; and

wherein the reduction of pyroglutamic acid to normal levels in said samples correlates with the amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) sufficient to achieve a beneficial effect.

23. (Withdrawn) A method for determining the amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) that is necessary to reduce urine lipid peroxide in a patient in need of such therapy, comprising the steps of:

- a) collecting a series of urine samples from a patient suspected of being in need of such treatment, wherein said samples are collected prior to the start of treatment, and daily after the start of treatment for about 14 days;
- b) measuring the amount of lipid peroxide in said samples;
- c) comparing the amount of lipid peroxide in said samples with that of a normal standard; and

wherein the reduction of lipid peroxide to normal levels in said samples correlates with the amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) sufficient to achieve a beneficial effect.

24. (Withdrawn) A method for determining an orally anti-oxidative effective amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) sufficient to diminish urine lipid peroxide and pyroglutamic acid levels and concurrently increase blood plasma glutathione levels, comprising the steps of:

- a) collecting blood plasma and urine samples prior to administration of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) and daily after the start of administration for about 14 days;
- b) measuring urine levels of lipid peroxide and pyroglutamic acid;
- c) measuring blood plasma glutathione levels;
- d) determining whether a decrease in lipid peroxide and pyroglutamic acid levels correlates with an increase in glutathione levels; and

wherein said correlation establishes an orally anti-oxidative effective amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM).

25. (Withdrawn) A method for establishing the interdependence of lipid peroxides, pyroglutamic acid, glutathione, and immune cell number and/or function in a subject suffering from oxidative stress, comprising the steps of:

- a) collecting a urine sample from a subject suspected of being under oxidative stress;
- b) assaying the urine for the presence of lipid peroxides and pyroglutamic acid;
- c) collecting a sample of whole blood;
- d) separating the cellular components from the liquid portion of whole blood;
- e) measuring glutathione in the liquid portion of whole blood obtained in step d);
- f) measuring the number of CD4+ and CD8+ T cells in the cellular component of whole blood from step d); and
- g) measuring the natural killer cell activity from the cellular component of whole blood obtained from step d);

wherein a finding of decreased plasma glutathione levels, an increase in urinary lipid peroxides and pyroglutamic acid, and a decrease in the number of CD4+ and CD8+ T cells and natural killer cell activity provides support for the interdependence of the level of oxidative stress in said subject and immune cell number and/or function.

26. (Withdrawn) A method for determining an immune enhancing effective amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) sufficient to normalize CD4+, CD8+ T cell numbers and natural killer cell activity in a subject suspected of experiencing oxidative stress, comprising the steps of:

- a) collecting whole blood samples prior to administration of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) and daily after the start of administration for about 14 days;
- b) separating the cellular component of the whole blood from the liquid component; and
- c) measuring the number of CD4+ and CD8+ T cells and natural killer cell activity using the cellular component from step b);

wherein a correlation between the dose of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) that is sufficient to normalize CD4+, CD8+ T cell numbers and natural killer cell activity establishes an immune enhancing effective amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM).

27. (Withdrawn) A method for determining an orally anti-oxidative effective amount and an immune enhancing effective amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) sufficient to normalize lipid peroxides, pyroglutamic acid and glutathione levels in a subject suspected of experiencing oxidative stress, wherein said normalization of lipid peroxides, pyroglutamic acid and glutathione levels results in immune enhancement, comprising the steps of:

- a) collecting whole blood and urine samples prior to administration of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) and daily after the start of administration for about 14 days;
- b) measuring urine levels of lipid peroxide and pyroglutamic acid;
- c) separating the cellular component of the whole blood from the liquid component;
- d) measuring blood plasma glutathione levels using the liquid component from step c);
- e) measuring the number of CD4+ and CD8+ T cells and natural killer cell activity using the cellular component from step c);
- f) determining whether a decrease in urinary lipid peroxide and pyroglutamic acid levels correlates with an increase in glutathione levels, and whether the normalization of the levels of all three of these products relates to a normalization of CD4+ and CD8+ T cell numbers and normalization of natural killer cell activity; and wherein said correlation establishes an orally anti-oxidative effective amount and an immune enhancing effective amount of IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM).

28. (Withdrawn) The method of claim 27, wherein said correlation further establishes the interrelationship of lipid peroxides, pyroglutamic acid, glutathione

and immune functions as compared to the level of oxidative stress in said subject which may result in depressed immune functions.

29. (Withdrawn) A kit for measuring oxidative stress in a subject comprising:

a) a solid substrate containing immobilized binding partners specific for at least three markers for oxidative stress;

b) either:

i) an enzyme conjugated second binding partner to the oxidative stress markers; or

ii) a biotinylated second binding partner to the oxidative stress markers;

c) either:

i) the enzyme substrate and the developing reagents specific for the enzyme conjugated second binding partner from step b) i); or

ii) a streptavidin conjugated third binding partner specific for the second binding partner of step b) ii);

d) buffers for washing and sample dilution;

e) standards for each of the at least three markers of oxidative stress; and

f) instructions for use of said kit.

30. (Withdrawn) The kit of claim 29, further comprising additional binding partners specific for cell surface markers for CD4+ T cells, CD8+ T cells and natural killer cells.

31. (Withdrawn) The kit of claim 29, wherein said markers of oxidative stress are selected from the group consisting of lipid peroxide, pyroglutamic acid and glutathione.

32. (Withdrawn) The kit of claim 29, wherein said binding partner is an antibody selected from the group consisting of a monoclonal antibody, a polyclonal antibody, a chimeric antibody, and any combination thereof.

33. (Withdrawn) A method for providing a course of therapy for an individual suspected or known to be suffering from oxidative stress comprising

- a) determining the identity and level of at least three markers of oxidative stress in a sample of body fluid from said individual in accordance with claim 29, said markers being indicative of the extent of oxidative stress; and
- b) selecting the appropriate course of therapy for said individual suffering from oxidative stress and the sequelae thereof.

34. (Withdrawn) The method of claim 33, which further includes administering said appropriate course of therapy to said individual.

35. (Withdrawn) A method for providing a course of therapy for an individual suspected or known to be suffering from oxidative stress and monitoring the success of said therapy comprising:

- a) determining the identity and level of at least three markers of oxidative stress in a sample of body fluid from said individual in accordance with claim 29, said marker indicative of the extent of oxidative stress;
- b) selecting the appropriate course of therapy for said individual suffering from said oxidative stress;
- c) administering said appropriate course of therapy to said individual; and monitoring the success of said therapy by measuring a normalization in levels of said markers of oxidative stress.

36. (Withdrawn) The method of any of claims 33-35, wherein said course of therapy comprises administering IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM) to said individual.

37. (Withdrawn) A method for assessing the need for treatment of a subject with an anti-oxidant comprising the steps of:

- a) collecting a sample of body fluid from a subject suspected of needing such

treatment;

b) measuring the amount of lipid peroxide and pyroglutamic acid levels in said sample;

c) measuring the level of blood plasma glutathione;

d) comparing the amount of lipid peroxide and pyroglutamic acid in said sample with that of a normal standard; and

e) comparing the level of blood plasma glutathione with that of a normal standard; and

wherein the presence of lipid peroxide and pyroglutamic acid in said sample and the blood plasma levels of glutathione are present in amounts that lie outside a range of the normal standards are indicative of a need for anti-oxidant treatment.

38. (Withdrawn) The method of claim 37, wherein said subject in need of treatment with an anti-oxidant also experiences a reduction in immune cell number and/or function of the immune cells.

39. (Withdrawn) The method of claim 38, wherein said immune cell is selected from the group consisting of a T cell, a B cell or a natural killer cell.

40. (Withdrawn) The method of claim 39, wherein said T cell is selected from the group consisting of a CD4+ T cell or a CD8+ T cell.

41. (Withdrawn) The method of claim 37, wherein said anti-oxidant comprises a formulation consisting of a glutathione precursor, wherein said glutathione precursor is IMMUNE FORMULATION 100(TM) or IMMUNE FORMULATION 200(TM).

42. (Withdrawn-Currently amended) A method for assessing the need for treatment of a subject with an anti-oxidant comprising the steps of:

a) collecting a sample of body fluid from a subject suspected of needing such treatment;

b) measuring the amount of lipid peroxide and pyroglutamic acid levels in said sample;

c) measuring the level of blood plasma glutathione;

d) comparing the amount of lipid peroxide and pyroglutamic acid in said sample with that of a normal standard; and

e) comparing the level of blood plasma glutathione with that of a normal standard; and

wherein the presence of lipid peroxide and pyroglutamic acid in said sample and the blood plasma levels of glutathione are present in amounts that lie outside a range of the normal standards are indicative of a need for anti-oxidant treatment

~~The method according to claim 37~~ wherein the antioxidant is a composition comprising a catalytic quantity of elemental selenium or a water soluble selenium precursor; from about 5% to about 95% by weight of the composition of a whey product containing from about 65% to about 85% protein which is from about 65% to about 100% denatured; and from about 5% to about 95% by weight of the composition of colostrum.

43. (Withdrawn) The method according to claim 37, wherein the antioxidant is a composition comprising a catalytic quantity of a selenium source together with a mixture of glutamic acid; cystine or a cystine precursor; and glycine wherein the glutamic acid; cystine or a cystine precursor; and glycine are in a ratio of 1:0.5:1.

44. (Withdrawn) The method of claim 37, wherein the sample of body fluid is urine.

45. (Currently amended) A method for measuring the effectiveness of anti-oxidant treatment ~~therapy with an anti-oxidant~~ in a subject ~~receiving treatment with an anti-oxidant~~ comprising the steps of:

a) collecting a sample of body fluid from ~~the~~ the subject being treated with an anti-oxidant;

b) measuring the amount of lipid peroxide and pyroglutamic acid in said sample;

c) measuring the level of blood plasma glutathione;
d) comparing the amount of lipid peroxide and pyroglutamic acid in said sample with that of a normal standard;
e) comparing the level of blood plasma glutathione with that of a normal standard;
and
wherein ~~the presence of~~ normal levels of lipid peroxide and pyroglutamic acid in said sample and ~~the presence of~~ normal levels of blood plasma glutathione are an indication of effectiveness of the treatment ~~anti-oxidant therapy~~.

46. (Currently amended) The method of claim 45, wherein said subject receiving treatment with ~~an~~ the anti-oxidant also experienced a reduction in immune cell number, ~~and/or~~ function or both prior to the start of treatment ~~therapy~~ with the anti-oxidant.

47. (Currently amended) The method of claim 46, further comprising determining whether immune cell number, ~~and/or~~ function or both is normalized in said subject, wherein said normalization is indicative of the effectiveness of ~~therapy~~ treatment with said anti-oxidant.

48. (Currently amended) The method of claim 47, wherein said immune cell is selected from the group consisting of a T cell, ~~a B cell or a~~ B cell and natural killer cell.

49. (Currently amended) The method of claim 48, wherein said T cell is selected from the group consisting of a CD4+ T cell ~~[[or a]]~~ and CD8+ T cell.

50. (Currently amended) The method of claim ~~51~~ 45, wherein said anti-oxidant ~~comprises a formulation consisting of a glutathione precursor, wherein said glutathione precursor is~~ composition is IMMUNE FORMULATION 100™ (TM) or IMMUNE FORMULATION 200(TM).

51. (Currently amended) The method according to claim 45, wherein the anti-oxidant ~~antioxidant~~ is a composition comprising a catalytic quantity of elemental selenium or a water soluble selenium precursor; from about 5% to about 95% by weight of ~~the composition of~~ a whey product containing from about 65% to about 85% protein, which is from about 65% to about 100% undenatured ~~denatured~~; and from about 5% to about 95% by weight of ~~the composition of~~ colostrum.

52. (Currently amended) The method according to claim 45, wherein the anti-oxidant ~~antioxidant~~ is a composition comprising a catalytic quantity of a selenium source together with a mixture of glutamic acid; cystine or a cystine precursor; and glycine, wherein the glutamic acid; cystine or a cystine precursor; and glycine are in a ratio of 1:0.5:1.

53. (Previously presented) The method of claim 45, wherein the sample of body fluid is urine.

54. (Previously presented) The method according to claim 45, wherein the presence of normal levels of lipid peroxide and pyroglutamic acid in said sample and the presence of normal levels of blood plasma glutathione are an indication of efficiency of utilization of the anti-oxidant.

55. (Currently amended) A method for assessing in a subject ~~the~~ need for treatment of ~~a subject~~ with an anti-oxidant or for assessing ~~the~~ effectiveness of said treatment, comprising the steps of:

- a) collecting one or more samples of body fluid from ~~[[a]]~~ the subject suspected of needing treatment with an anti-oxidant or ~~[[a]]~~ the subject who has been treated with ~~[[an-]]~~ the anti-oxidant;
- b) measuring the amount of lipid peroxide and pyroglutamic acid levels in said

sample;

c) measuring the level of blood plasma glutathione;

d) comparing the amount of lipid peroxide and pyroglutamic acid in said sample with that of a standard;

e) comparing the level of blood plasma glutathione with that of a standard;

wherein when the amount of lipid peroxide and pyroglutamic acid in said sample and the level of blood plasma glutathione are outside the standard, there is a need for anti-oxidant treatment and wherein when the amount of lipid peroxide and pyroglutamic acid in said sample and the level of blood plasma glutathione in said sample are within the standard, it is an indication of the effectiveness of the treatment with the anti-oxidant.

56. (Currently amended) The method according to claim 55, wherein the anti-oxidant ~~antioxidant~~ is a composition comprising a catalytic quantity of elemental selenium or a water soluble selenium precursor; from about 5% to about 95% by weight of the composition of a whey product containing from about 65% to about 85% protein, which is from about 65% to about 100% undenatured ~~denatured~~; and from about 5% to about 95% by weight of ~~the composition of~~ colostrum.

57. (Currently amended) The method according to claim 55, wherein the anti-oxidant ~~antioxidant~~ is a composition comprising a catalytic quantity of a selenium source together with a mixture of glutamic acid; cystine or a cystine precursor; and glycine, wherein the glutamic acid; cystine or a cystine precursor; and glycine are in a ratio of 1:0.5:1.

58. (Currently amended) The method according to claim ~~55~~ 56, wherein the anti-oxidant ~~antioxidant~~ composition ~~comprises a formulation consisting of a glutathione precursor, wherein said glutathione precursor is IMMUNE FORMULATION 100™~~ ~~™ or IMMUNE FORMULATION 200™~~.

59. (Previously presented) The method according to claim 55, wherein at least one of the samples is urine.

60. (Currently amended) The method according to claim 55, further comprising measuring the number of immune cells in the sample and comparing the number to a standard~~[[+]]~~, wherein when the number of immune cells are less than the standard₁ there is a need for anti-oxidant treatment and wherein when the number of immune cells is within the standard₁ it is an indication of the effectiveness of the treatment with the anti-oxidant.

61. (Currently amended) The method according to claim 60, wherein the immune cell is selected from the group consisting of a T cell, ~~a B cell or a~~ B cell and natural killer cell.

62. (Previously presented) The method according to claim 61, wherein the T cell is selected from the group consisting of a CD4+ T cell ~~[[or a]]~~ and CD8+ T cell.

63. (New) The method according to claim 52 wherein the anti-oxidant composition is IMMUNE FORMULATION 200™.

64. (New) The method according to claim 57 wherein the anti-oxidant composition is IMMUNE FORMULATION 200™.